

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMPB

Display Date 5-23-03
Publication Date 5-24-03
Certifier J. White

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee;

Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee.

General Function of the Subcommittee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 11, 2003, from 8:30 a.m. to 5 p.m. and on June 12, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or e-mail: perezth@cder.fda.gov, or FDA Advisory Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

oc03150

OC 03150

NM

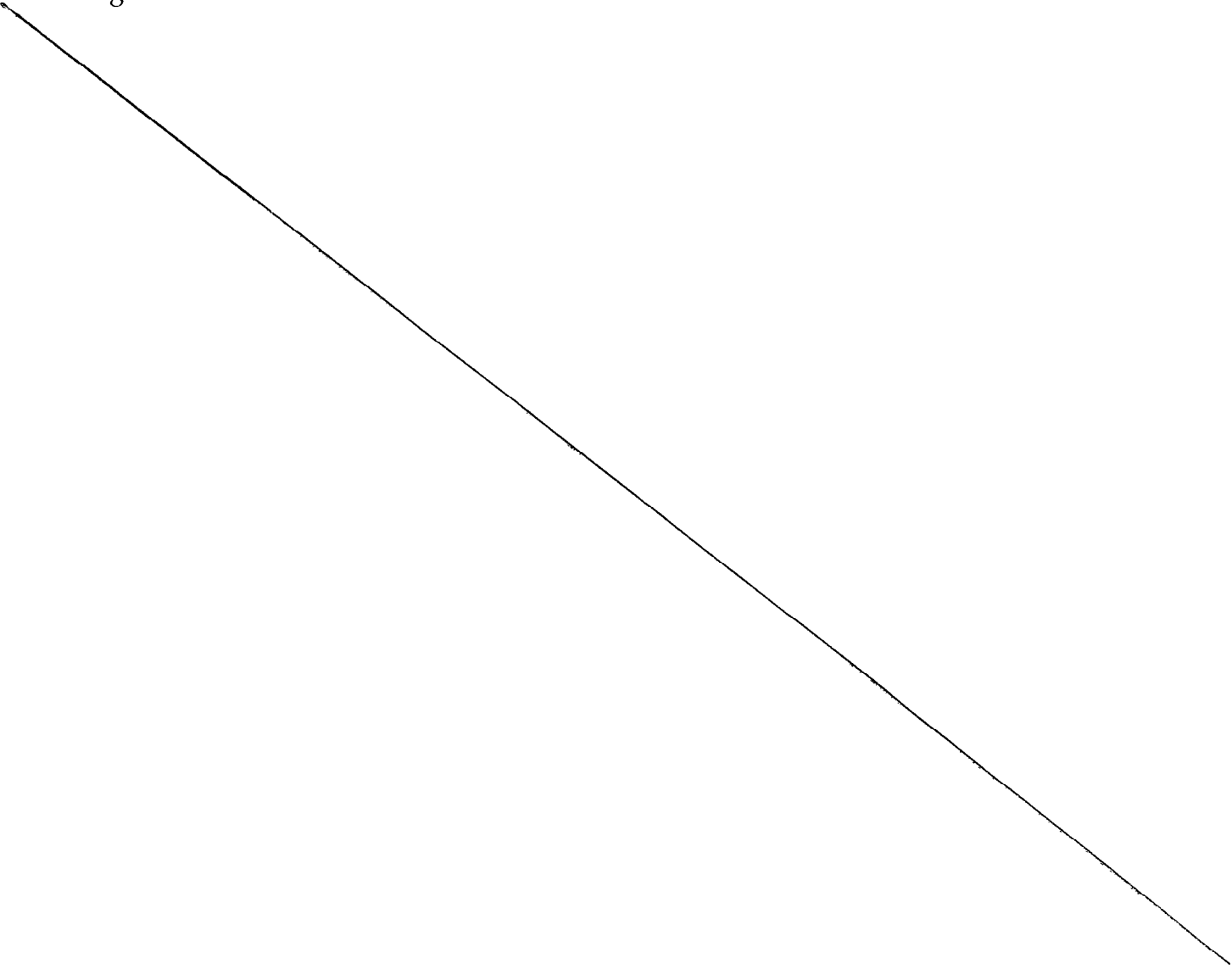
Agenda: On June 11, 2003, the subcommittee will discuss the current epidemiology and therapeutic interventions relevant to hyperbilirubinemia in the term and near-term newborn. On June 12, 2003, the subcommittee will begin with a closed session between 8 a.m. and 3 p.m. Following the closed session, there will be an open subcommittee meeting from approximately 3:15 p.m. to 5 p.m., where the agency will report to the subcommittee on adverse event reporting as mandated in section 17 of the Best Pharmaceuticals for Children Act. The products to be discussed during this portion of the meeting include ZOLOFT (sertraline) Pfizer Inc., and DITROPAN (oxybutynin) Alza Corp., with an interim update to be provided on LIPITOR (atorvastatin) Pfizer Inc., and ZOCOR (simvastatin) Merck & Co. Inc. The background material for this meeting will be posted on the Internet when available or 1-working day before the meeting at www.fda.gov/ohrms/dockets/ac/menu.htm.

Procedure: On June 11, 2003, from 8 a.m. to 5 p.m., the meeting is open to the public. On June 12, 2003, from 3:15 p.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by June 4, 2003. On June 11, 2003, oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. On June 12, 2003, oral presentations from the public will be scheduled between approximately 4:15 p.m. and 4:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by June 4, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Subcommittee Deliberations: On June 12, 2003, from 8 a.m. to 3 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Thomas Perez at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: 5/19/03
May 19, 2003.



Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

VERIFIED TO BE A TRUE
COPY OF THE ORIGINAL

